



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

May 10, 2017

Frederick T. Smith
Authorized Agent to Andermatt Biocontrol AG
SciReg, Inc.
12733 Director's Loop
Woodbridge, VA 22192

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10 – Addition of an
Alternate Brand Name
Product Name: Helicovex
EPA Registration Number: 69553-2
Application Date: 04/05/2017
OPP Decision Number: 528439

Dear Mr. Smith:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped "Notification" and will be placed in our records. The alternate brand name Bolldex has been added to the product's records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Page 2 of 2
EPA Reg. No. 69553-2
OPP Decision No. 528439

If you have any questions, please contact Elyse Bilardo by phone at (703) 347-0182 or via email at bilardo.elyse@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with several overlapping strokes and a long horizontal tail.

Jeannine Kausch, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Master Label

HELICOVEX®

ABN: BOLLDEX

Insecticidal Virus for Use in Greenhouses, Open Fields, and Home Gardens for the Control of the Corn earworm, the Tobacco budworm and the African cotton bollworm.

Sublabel A: Agricultural Use
Sublabel B: Residential Use



Formatiert: Schriftart: 22 Pt.

Active Ingredient:*

Helicoverpa armigera nucleopolyhedrovirus strain BV-0003 0.60%

Other Ingredients: 99.40%

Total: 100.00%

*Contains a minimum of 7.5×10^{12} viral occlusion bodies per liter.

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No.: 69553-2
EPA Est. No.:



Manufactured by: Andermatt Biocontrol AG
Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

NOTIFICATION

69553-2

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

05/10/2017

Master Label

SUBLABEL A: Agricultural Use
HELICOVEX®

ABN: BOLDEX

Insecticidal Virus for Use in Greenhouses and Open Fields for the Control of the Corn earworm, the Tobacco budworm and the African cotton bollworm.

 FOR ORGANIC PRODUCTION



Formatiert: Schriftart: 22 Pt.

Active Ingredient:*

Helicoverpa armigera nucleopolyhedrovirus strain BV-0003 0.60%

Other Ingredients: 99.40%

Total: 100.00%

*Contains a minimum of 7.5×10^{12} viral occlusion bodies per liter.

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/INSIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS
AND FIRST AID

Net Contents:

Lot No.:

EPA Reg. No.: 69553-2

EPA Est. No.:



Manufactured by: Andermatt Biocontrol AG
Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye and skin irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
If on skin:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information.	

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt and long pants
- waterproof gloves
- shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Mixers/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95 or P-95. Repeated exposures to high concentrations of microbial proteins can cause allergic sensitization.

Engineering Controls

When handlers use closed systems or enclosed cabs in a manner that meet the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must provide all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

USER SAFETY RECOMMENDATIONS

Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash waters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted entry intervals (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water, is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

GENERAL INFORMATION

SHAKE WELL BEFORE USING

HELICOVEX® acts very specifically against larvae of *Helicoverpa* sp., such as the corn earworm, *Helicoverpa zea* (also known as cotton bollworm, tomato fruitworm), the tobacco budworm *Helicoverpa virescens* and the African cotton bollworm *Helicoverpa armigera*. After ingestion by the larva, the virus multiplies within the cells of the host insect causing a fatal infection. Rapid virus multiplication within the host cells results in cell destruction and death of the organism, typically within 3-7 days.

Application

Start spraying before larvae hatch from the eggs and onto young instar larvae after hatching. If moths are still flying and laying eggs, re-apply as directed in the table below. Due to certain weather conditions, such as lower temperatures, the flight, egg laying, and hatching may extend over a longer period of time making more applications necessary. Frequent applications at low rates may be more effective than one or two applications at high rates.

Use sufficient water to obtain thorough, uniform coverage. Because HELICOVEX® acts through ingestion of treated plant material, thorough spray coverage is essential for optimum control of targeted pest insects. Using increased water volumes will typically result in better spray coverage, especially under adverse conditions such as dry hot weather or dense plant foliage.

For greenhouse applications: the re-application interval can be extended to 7-14 days, because of reduced UV-radiation. In general, 2 to 3 sprays per pest generation are usually sufficient. However, at fast plant growth make sure to cover young tissue with intervals of 6-8 days.

For chemigation applications: see "CHEMIGATION" section of this label for guidance.

Tank Mixes

HELICOVEX® is compatible with most commonly used insecticides, fungicides or liquid fertilizers. Avoid tank mixes with copper products. Otherwise the protective protein capsule will be destroyed and the active substance inactivated. Spraying of copper a few days before or after a HELICOVEX® application has no adverse effect.

It is not necessary to add feeding stimulants, surfactant/wetting agents, or other adjuvants, though use of a non-ionic or oil-based spreader/sticker and ultraviolet screening agent may enhance the performance of this product. Silicone-based spreaders may interfere with adhesion of virus particles to the plant surface and should not be used with this product.

Fill the mix tank with desired quantity of clean water. Ideal pH is between 5 and 8.5; adjust highly alkaline (pH>8.5) or acidic (pH<5) water to a pH around 7 with a

Master Label

buffering agent before adding HELICOVEX®. Shake the HELICOVEX® container well, or invert it several times before pouring to ensure uniform suspension. Keep the tank agitated during mixing. If a spreader/sticker or ultraviolet screen is used, add prior to the addition of HELICOVEX®. Mixing time can be reduced by premixing HELICOVEX® with a small amount of clean water and agitating vigorously before adding to the tank. Spray as soon as possible after mixing; do not allow the spray mix to stand overnight.

CROPS (including but not limited to)	APPLICATION RATE	APPLICATION METHOD	EQUIPMENT	COMMENTS
<p>Tomatoes; lettuce; cucumbers; peppers; sweet corn; broccoli, cauliflower, cabbage; peas; beans, beets; celery; onions; garlic, leek, asparagus; okra; eggplant strawberries, grapes, escarole ornamentals and flowers</p> <p>Cotton, alfalfa, soybeans, peanuts, potatoes, corn, wheat, sweet potatoes, tobacco, sunflowers, sugar beets, sorghum, floriculture and border plants</p>	<p>1.0 - 2.5 fl. oz. per acre</p>	<p>Sprayer, Aircraft</p>	<p>Sprayer, Sprinkler Irrigation, Mist Sprayer</p>	<p>Repeat application as above every 6 - 8 sunny days (counting 2 partially sunny days as 1 sunny day) if monitoring indicates that reapplication is necessary.</p> <p>Lower rates (every 6 sunny days) may be used during vegetative stages of the crop or when tank mixed with other insecticides.</p> <p>When flowers, fruits or other harvested structures of the plant are present or when infestation becomes strong, use the higher rates.</p> <p>Sweet corn and corn: For very sunny regions (e.g., California), use 0.5 to 1.25 fl. oz./acre every 3 days; for less sunny regions, use 1 to 2.5 fl. oz./acre every 6 to 8 days.</p> <p>Cover the whole larval hatching period of the treated generation until harvest.</p>

HELICOVEX® can be applied up to and including the day of harvest.

Master Label

Aerial applications

Apply in a minimum of 5 gallons of spray solution per acre by aircraft spray equipment. Aerial applications made to dense canopies may not provide sufficient coverage of lower leaves to provide acceptable pest control. Under these conditions, the higher rate of HELICOVEX Insecticide specified in the crop specific tables within the Directions for Use section of this label may be necessary for optimum pest control. If application in water by air during hot and dry conditions cannot be avoided, increase application volume and/or use an anti-evaporation additive (such as an emulsifiable oil) to improve coverage.

CHEMIGATION

Apply this product only through pressurized sprinkler irrigation systems (impact or micro sprinklers overhead boom, solid set, lateral move, end tow, side-roll, center pivot, or hand move, including mist-type systems). Do not apply this product through any other type of irrigation system.

Crop injury or lack of effectiveness can result from non-uniform distribution of treated water.

If you have questions about calibration, contact State Extension Service specialists, equipment manufacturers or other experts.

Do not connect an irrigation system (including greenhouse systems) used for pesticide application to a public water system unless the pesticide label-prescribed safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under the supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

Public water system means a system for the provision to the public of piped water for human consumption if such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the flow outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection.

Master Label

The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.

The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and injector system and flush with clean water before use. Failure to provide a clean tank, free of scale or residues may reduce effectiveness of this product.

Master Label

SPRINKLER CHEMIGATION:

1. The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
2. The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
3. The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
4. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
5. The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.
6. Systems must use a metering pump, such as a positive displacement injection pump (i.e., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.
7. Dilute the product in water following the label mixing directions. It may be premixed in a supply tank with water, fertilizer or other appropriate tank-mixed agricultural chemicals. Agitation is necessary. Application should be continuous in sufficient water to apply the recommended rate evenly to the entire treated area.
8. Do not apply when wind speed favors drift beyond the area intended for treatment.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE:

Store this product in original sealed container in a cool, dry place inaccessible to children and pets. Store at temperatures below 41°F (5°C). Bioactivity may be impaired by storage above 86°F (30°C). Storing the product under cold or freezing temperatures will extend its shelf life.

PESTICIDE DISPOSAL:

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local

Master Label

governments or by industry).

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain 10 seconds after the flow begins to drip. Fill the container 1/4 full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. Do not burn, unless allowed by State and local ordinances. If burned, stay out of smoke.

WARRANTY

Andermatt Biocontrol AG warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

Master Label

Sublabel B: Residential Use

HELICOVEX®

ABN: BOLLDEX

Insecticidal Virus for Use in Greenhouses and Home Gardens for the Control of the Corn earworm, the Tobacco budworm and the African cotton bollworm



FOR ORGANIC GARDENING



Formatiert: Schriftart: 22 Pt.

Active Ingredient*:

Helicoverpa armigera nucleopolyhedrovirus strain BV-0003 0.60%

Other Ingredients: 99.40%

Total: 100.00%

*Contains a minimum of 7.5×10^{12} viral occlusion bodies per liter.

KEEP OUT OF REACH OF CHILDREN

CAUTION

SEE SIDE/INSIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND FIRST AID



Net Contents:

Lot No.:

EPA Reg. No.: 69553-2

EPA Est. No.:

Manufactured by: Andermatt Biocontrol AG
Stahlermatten 6
CH-6146 Grossdietwil
Switzerland

Feb. 5, 2016

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wear goggles or safety glasses. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before use.

FIRST AID	
If in eyes:	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.• Call a poison control center or doctor for treatment advice.
If on skin:	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
HOT LINE NUMBER Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information.	

ENVIRONMENTAL HAZARDS

To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Rinsing application equipment over the treated area will help avoid run off to water bodies or drainage systems.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

GENERAL INFORMATION

SHAKE WELL BEFORE USING

HELICOVEX® acts very specifically against larvae of *Helicoverpa* sp., such as the corn earworm, *Helicoverpa zea* (also known as cotton bollworm, tomato fruitworm), the tobacco budworm *Helicoverpa virescens* and the African cotton bollworm *Helicoverpa armigera*.

After ingestion by the larva, the virus multiplies within the cells of the host insect causing a fatal infection. Rapid virus multiplication within the host cells results in cell destruction and death of the organism, typically within 3-7 days.

Master Label

Use Restrictions

For use only on fruits, vegetables, and flowers in residential settings. Not for use on agricultural crops for sale or other commercial use.

MIXING AND APPLICATION INSTRUCTIONS

Mix HELICOVEX® with water and apply as a spray to crops. Use water at pH between 5 and 8.5.

Mix 1/2 teaspoon of HELICOVEX® per 3 gallons of water and apply to all plant foliage to cover an area of 1000 square feet. Apply at first sign of infestation and repeat at weekly intervals when needed to maintain control of *Helicoverpa* larvae on tomatoes, lettuce, cabbage, beans, peppers, potatoes, celery, escarole, sweet corn, peas, asparagus, beets, cauliflower, cucumber, broccoli, onion, strawberries, okra, ornamentals, flowers, and other vegetables. For corn, apply on 1/4 teaspoon of HELICOVEX® per 3 gallons of water on 3 day intervals for very sunny regions (e.g., California) and 1/2 teaspoon of HELICOVEX® per 3 gallons of water every 6-8 days for less sunny regions, if monitoring indicates that reapplication is necessary.

Start spraying shortly before larvae hatch from the eggs and before the larvae grow bigger and cause more serious damage. In general, 2 to 3 sprays per generation are sufficient. Due to weather conditions (e.g. cooler temperatures), the flight, egg-laying, and hatching may extend over a longer period of time and more applications may be needed to cover the entire hatching period.

For greenhouse applications: the re-application interval can be extended to 7-14 days, because of reduced UV-radiation. In general, 2 to 3 sprays per pest generation are usually sufficient. However, at fast plant growth make sure to cover young tissue with intervals of 6-8 days.

HELICOVEX® can be applied up to and including the day of harvest.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage and disposal.

PESTICIDE STORAGE:

Keep in original container. Store away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Store at temperatures below 41°F (5°C). Bioactivity may be impaired by storage above 86°F (30°C). Storing the product under cold or freezing temperatures will extend its shelf life.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. Do not reuse or refill this container.

If empty:

Place in trash or offer for recycling, if available.

If partly filled:

Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Master Label

WARRANTY

Andermatt Biocontrol AG warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended and other influencing factors in the use of this product are beyond the control of the seller. To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. To the extent consistent with applicable law, NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.